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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/714,643

11/18/2003

Peter A. Crooks

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EXAMINER

CHONG, YONG SOO

ART UNIT

PAPER NUMBER

1617

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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31 DAYS

03/30/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/714,643

Applicant(s)

CROOKS ET AL.

Examiner

Yong S. Chong

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-72 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____ | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Election/Restrictions

Restriction to the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-31, 71 (in part) are drawn to a method for treating pain in a subject comprising administering a compound of formula 1 or 2, where R2 is not cyclic, classified in 514/646.
- II. Claims 1-31, 71 (in part) are drawn to a method for treating pain in a subject comprising administering a compound of formula 1 or 2, where R2 is a carbocycle, classified in 514/678.
- III. Claims 1-31, 71 (in part) are drawn to a method for treating pain in a subject comprising administering a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one nitrogen, classified in 514/408.
- IV. Claims 1-31, 71 (in part) are drawn to a method for treating pain in a subject comprising administering a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one oxygen, classified in 514/461.
- V. Claims 1-31, 71 (in part) are drawn to a method for treating pain in a subject comprising administering a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing two oxygens, classified in 514/463.
- VI. Claims 32-68 (in part) are drawn to a device comprising a nasal applicator containing a formulation comprising a compound of formula 1 or 2, where R2 is not cyclic, and a pharmaceutically acceptable vehicle, classified in 514/646.
- VII. Claims 32-68 (in part) are drawn to a device comprising a nasal applicator containing a formulation comprising a compound of formula 1 or 2, where R2 is a carbocycle, and a pharmaceutically acceptable vehicle, classified in 514/678.
- VIII. Claims 32-68 (in part) are drawn to a device comprising a nasal applicator containing a formulation comprising a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one nitrogen, and a pharmaceutically acceptable vehicle, classified in 514/408.

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- IX. Claims 32-68 (in part) are drawn to a device comprising a nasal applicator containing a formulation comprising a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one oxygen, and a pharmaceutically acceptable vehicle, classified in 514/461.
- X. Claims 32-68 (in part) are drawn to a device comprising a nasal applicator containing a formulation comprising a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing two oxygens, and a pharmaceutically acceptable vehicle, classified in 514/463.
- XI. Claims 69-70, 72 (in part) are drawn to a compound of formula 1 or 2, where R2 is not cyclic, classified in 514/646.
- XII. Claims 69-70, 72 (in part) are drawn to a compound of formula 1 or 2, where R2 is a carbocycle, classified in 514/678.
- XIII. Claims 69-70, 72 (in part) are drawn to a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one nitrogen, classified in 514/408.
- XIV. Claims 69-70, 72 (in part) are drawn to a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing one oxygen, classified in 514/461.
- XV. Claims 69-70, 72 (in part) are drawn to a compound of formula 1 or 2, where R2 is a 5-membered heterocycle containing two oxygens, classified in 514/463.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-V and VI-XV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, there are many other methods of treating pain with drugs containing different core structures, such as ibuprofen.

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Inventions VI-XV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the different inventions are totally different compounds because of the varying core structures. Having different structures leads to different reactivity, binding affinity, mechanism, stability, polarity, bioavailability, efficacy, solubility, and modes of action. Furthermore, the search for one will not lead to information regarding another, and vice versa. Because these inventions are distinct for the reasons given above and the search required for one invention is not required for another, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to

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be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai*, *In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

Species Election

This application contains claims directed to more than one species of the generic invention.

The species are as follows:

- 1) a single disclosed compound of formula 1 or 2
- 2) a single disclosed type of pain, for example pain associated with labor

Applicant is further required to elect a single disclosed compound of formula 1 or 2 from subsection 1 and a single disclosed type of pain from subsection 2. Currently, claims 1-72 are generic to a plurality of disclosed patentably distinct species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species, even though this requirement is traversed. Note the court in *In re Herrick et al.* and *In re Joyce et al.* (both at 115 USPQ 412) held that an election of species requirement was, in fact, a restriction requirement.

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Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement is traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

A telephone call to the attorney is not required where: 1) the restriction requirement is complex, 2) the application is being prosecuted pro se, or 3) the examiner knows from past experience that a telephone election will not be made (MPEP § 812.01). Therefore, since this restriction requirement is considered complex, a call to the attorney for telephone election was not made.

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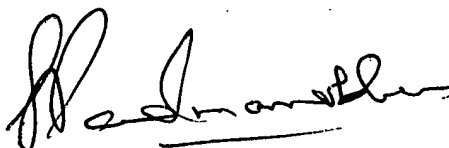
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong S. Chong whose telephone number is (571)-272-8513. The examiner can normally be reached on M-F, 9-6.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, SREENI PADMANABHAN can be reached on (571)-272-0629. The fax phone number for the organization where this application or proceeding is assigned is (571)-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

YSC


SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER